

해외 의약품 인허가 현황 (2020.3.30~2020.4.5.)

한국바이오의약품협회, 2020.4.7.

○ 미국 2건 (출처: FDA)

Approval date	Drug name	Active Ingredients	Submission Classification	Company	비고
03/27/2020	TRIFERICNDA #212860	FERRIC PYROPHOSPHATE CITRATE	신용량	ROCKWELL MEDICAL INC	
03/30/2020	LEVONORGESTREL AND ETHINYL ESTRADIOLNDA #209405	ETHINYL ESTRADIOL; LEVONORGESTREL	신용량	EXELTIS USA INC	

○ 유럽 2건 (출처: EMA)

Approval date	Drug name	Active Ingredients	Therapeutic area	Marketing-authorisation holder	비고
24/03/2020	Azacitidine betapharm	Azacitidine	<ul style="list-style-type: none"> Myelodysplastic Syndromes Leukemia, Myelomonocytic, Chronic Leukemia, Myeloid, Acute 	betapharm Arzneimittel GmbH	
27/03/2020	Nubeqa	Darolutamide	Prostatic Neoplasms, Castration-Resistant	Bayer AG	

○ 일본 18건 (출처: PMDA)

승인연월(承認日)	판매명(販売名)	일반명/성분명(成分名)	분야(分野)	업체명(会社名)	비고
2020.3.25	LYUMJEV Injection	Insulin Lispro(Genetical Recombination)	호르몬 제제, 대사질환약(예. 항당뇨, 골다공증, 통풍, 선천성 대사질환의약품)	Eli Lilly Japan	바이오의약품
2020.3.25	Beovu Intravitreal Injection 120 mg/mL	brolicizumab	마취제, 감각기관 의약품(염증질환의약품 외), 마약	Novartis Pharma Corporation	바이오의약품
2020.3.25	Soliqua 배합주 SoloStar	Insulin Gluligine	호르몬 제제, 대사질환약(예. 항당뇨, 골다공증, 통풍, 선천성 대사질환의약품)	Sanofi K.K.	바이오의약품
2020.3.25	VONVENDI Intravenous 1300	Vonicog Alfa (Genetical Recombination)	혈액제제	Shire Japan	바이오의약품
2020.3.25	ENHERTU FOR INTRAVENOUS DRIP INFUSION 100mg	Trastuzumab Deruxtecan (Genetical Recombination)	항종양제	DAIICHI SANKYO COMPANY, LIMITED	바이오의약품
2020.3.25	Insulin Lispro BS Injection HU 「Sanofi」	Insulin Lispro(Genetical Recombination)	바이오 품질, 바이오시밀러	Sanofi K.K.	바이오의약품
2020.3.25	ONIVYDE Intravenous Infusion 43mg	Irinotecan Hydrochloride Hydrate	항종양제	NIHON SERVIER	
2020.3.25	Baqsimi® Nasal Powder 3mg	Glucagon	호르몬 제제, 대사질환약(예. 항당뇨, 골다공증, 통풍, 선천성 대사질환의약품)	Eli Lilly Japan	
2020.3.25	CABOMETYX tablets 20mg 同 tablets 60mg	Cabozantinib Malate	항종양제	Takeda Pharmaceutical Industries, Ltd.	
2020.3.25	Melatobel granules 0.2% for pediatric	Melatonin	중추신경계 의약품, 말초신경계 의약품 (마취제 제외)	Nobelpharma Co., Ltd	
2020.3.25	AILAMIDE COMBINATION OPHTHALMIC SUSPENSION	Brimonidine Tartrate	마취제, 감각기관 의약품(염증질환의약품 외), 마약	Senju Pharmaceutical Co.,Ltd.	
2020.3.25	Lokelma 5g powder for suspension (single-dose package) 同 10g powder for suspension (single-dose package)	Sodium Zirconium Cyclosilicate Hydrate	위장약, 피부과 의약품	AstraZeneca	
2020.3.25	CABPIRIN Combination Tablets	Vonoprazan Fumarate	심혈관의약품, 파킨슨병 치료제, 알츠하이머병 치료제	Takeda Pharmaceutical Industries, Ltd.	
2020.3.25	Latuda tablets 20mg 同 tablets 40mg 同 tablets 60mg 同 tablets 80mg	Lurasidone Hydrochloride	중추신경계 의약품, 말초신경계 의약품 (마취제 제외)	Sumitomo Dainippon Pharma Co., Ltd.	
2020.3.25	VELEXBRU Tablets 80mg	Tirabrutinib Hydrochloride	항종양제	ONO PHARMACEUTICAL CO, LTD.	
2020.3.25	Viltepso Injection 250mg	Viltolarsen	중추신경계 의약품, 말초신경계 의약품 (마취제 제외)	NIPPON SHINYAKU CO.,LTD	
2020.3.25	Steboronine Intravenous Drip Bag 9000mg/300mL	Boropharan [10B]	항종양제	STELLA PHARMA CORPORATION	
2020.3.25	TEPMETKO Tablets 250mg	Tepotinib Hydrochloride Hydrate	항종양제	Merck KGaA	